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ROTHWELL, FIGG, ERNST & MANBECK, P.C.
1425 K STREET, N.W.
SUITE 800
WASHINGTON, DC 20005

EXAMINER	
UNGAR, SUSAN NMN	

ART UNIT	PAPER NUMBER
1642	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/003,463	MOLINA ET AL.	
	Examiner	Art Unit	
	Susan Ungar	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *06 December 2001*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) *1-24* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. Claims 1-24 are pending in the application and are currently under prosecution.

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

3. Claims 1, 2, 3, 9, link inventions 1-18/(A)-(N). The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 1-3, 9. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP 804.01.

Group 1. Claims 1-11, 14 drawn to a composition that potentiates immunogenicity comprising peptide/polypeptide, protein antigen which is a growth factor receptor, HER-1 wherein the incorporated ganglioside is GM1 or variant thereof, wherein the adjuvant is oily adjuvant, incomplete Freund□s Adjuvant, Montanide ISA51 classified in Class 530, subclass 350, Class 424, subclasses 1.11, 1.21.

Group 2. Claims 1-11, 14 drawn to a composition that potentiates immunogenicity comprising peptide/polypeptide, protein antigen which is a

growth factor receptor, HER-2 wherein the incorporated ganglioside is GM1 or variant thereof, wherein the adjuvant is oily adjuvant, incomplete Freund□s Adjuvant, Montanide ISA51 classified in Class 530, subclass 350, Class 424, subclasses 1.11, 1.21

Group 3. Claims 1-11, 14 drawn to a composition that potentiates immunogenicity comprising peptide/polypeptide, protein antigen which is a growth factor receptor, PDGF-R wherein the incorporated ganglioside is GM1 or variant thereof, wherein the adjuvant is oily adjuvant, incomplete Freund□s Adjuvant, Montanide ISA51 classified in Class 530, subclass 350, Class 424, subclasses 1.11, 1.21.

Group 4. Claims 1-11, 14 drawn to a composition that potentiates immunogenicity comprising peptide/polypeptide, protein antigen which is a growth factor receptor, HER-1 wherein the incorporated ganglioside is GM3 or variant thereof, wherein the adjuvant is oily adjuvant, incomplete Freund□s Adjuvant, Montanide ISA51 classified in Class 530, subclass 350, Class 424, subclasses 1.11, 1.21.

Group 5. Claims 1-11, 14 drawn to a composition that potentiates immunogenicity comprising peptide/polypeptide, protein antigen which is a growth factor receptor, HER-2 wherein the incorporated ganglioside is GM3 or variant thereof, wherein the adjuvant is oily adjuvant, incomplete Freund□s Adjuvant, Montanide ISA51 classified in Class 530, subclass 350, Class 424, subclasses 1.11, 1.21.

Group 6. Claims 1-11, 14 drawn to a composition that potentiates immunogenicity comprising peptide/polypeptide, protein antigen which is a growth factor receptor, PDGF-R wherein the incorporated ganglioside is

GM3 or variant thereof, wherein the adjuvant is oily adjuvant, incomplete Freund□s Adjuvant, Montanide ISA51 classified in Class 530, subclass 350, Class 424, subclasses 1.11, 1.21.

Group 7. Claims 1-9, 12-14 drawn to a composition that potentiates immunogenicity comprising peptide/polypeptide, protein antigen which is a growth factor receptor, HER-1 wherein the incorporated ganglioside is GM1 or variant thereof, wherein the adjuvant is polypeptide/cytosine/GMC classified in Class 530, subclass 350, Class 424, subclasses 1.11, 1.21.

Group 8. Claims 1-9, 12-14 drawn to a composition that potentiates immunogenicity comprising peptide/polypeptide, protein antigen which is a growth factor receptor, HER-2 wherein the incorporated ganglioside is GM1 or variant thereof, wherein the adjuvant is polypeptide/cytosine/GMC classified in Class 530, subclass 350, Class 424, subclasses 1.11, 1.21.

Group 9. Claims 1-9, 12-14 drawn to a composition that potentiates immunogenicity comprising peptide/polypeptide, protein antigen which is a growth factor receptor, PDGF-R wherein the incorporated ganglioside is GM1 or variant thereof, wherein the adjuvant is polypeptide/cytosine/GMC classified in Class 530, subclass 350, Class 424, subclasses 1.11, 1.21.

Group 10. Claims 1-9, 12-14 drawn to a composition that potentiates immunogenicity comprising peptide/polypeptide, protein antigen which is a growth factor receptor, HER-1 wherein the incorporated ganglioside is GM3 or variant thereof, wherein the adjuvant is polypeptide/cytosine/GMC classified in Class 530, subclass 350, Class 424, subclasses 1.11, 1.21.

Group 11. Claims 1-9, 12-14 drawn to a composition that potentiates immunogenicity comprising peptide/polypeptide, protein antigen which is a

growth factor receptor, HER-2 wherein the incorporated ganglioside is GM3 or variant thereof, wherein the adjuvant is polypeptide/cytosine/GMC classified in Class 530, subclass 350, Class 424, subclasses 1.11, 1.21.

Group 12. Claims 1-9, 12-14 drawn to a composition that potentiates immunogenicity comprising peptide/polypeptide, protein antigen which is a growth factor receptor, PDGF-R wherein the incorporated ganglioside is GM3 or variant thereof, wherein the adjuvant is polypeptide/cytosine/GMC classified in Class 530, subclass 350, Class 424, subclasses 1.11, 1.21.

Group 13. Claims 1-9, 12,14 drawn to a composition that potentiates immunogenicity comprising peptide/polypeptide, protein antigen which is a growth factor receptor, HER-1 wherein the incorporated ganglioside is GM1 or variant thereof, wherein the adjuvant is polypeptide/chymosin classified in Class 530, subclass 350, Class 424, subclasses 1.11, 1.21.

Group 14. Claims 1-9, 12,14 drawn to a composition that potentiates immunogenicity comprising peptide/polypeptide, protein antigen which is a growth factor receptor, HER-2 wherein the incorporated ganglioside is GM1 or variant thereof, wherein the adjuvant is polypeptide//chymosin classified in Class 530, subclass 350, Class 424, subclasses 1.11, 1.21.

Group 15. Claims 1-9, 12,14 drawn to a composition that potentiates immunogenicity comprising peptide/polypeptide, protein antigen which is a growth factor receptor, PDGF-R wherein the incorporated ganglioside is GM1 or variant thereof, wherein the adjuvant is polypeptide//chymosin classified in Class 530, subclass 350, Class 424, subclasses 1.11, 1.21.

Group 16. Claims 1-9, 12,14 drawn to a composition that potentiates immunogenicity comprising peptide/polypeptide, protein antigen which is a

growth factor receptor, HER-1 wherein the incorporated ganglioside is GM3 or variant thereof, wherein the adjuvant is polypeptide//chymosin classified in Class 530, subclass 350, Class 424, subclasses 1.11, 1.21.

Group 17. Claims 1-9, 12,14 drawn to a composition that potentiates immunogenicity comprising peptide/polypeptide, protein antigen which is a growth factor receptor, HER-2 wherein the incorporated ganglioside is GM3 or variant thereof, wherein the adjuvant is polypeptide//chymosin classified in Class 530, subclass 350, Class 424, subclasses 1.11, 1.21.

Group 18. Claims 1-9, 12,14 drawn to a composition that potentiates immunogenicity comprising peptide/polypeptide, protein antigen which is a growth factor receptor, PDGF-R wherein the incorporated ganglioside is GM3 or variant thereof, wherein the adjuvant is polypeptide//chymosin classified in Class 530, subclass 350, Class 424, subclasses 1.11, 1.21.

For each of the inventions 1-18 above, restriction to one of the following is also required under 35 USC121. Therefore, election is required of one of inventions 1-18 **and** one of inventions (A)-(N).

(A) composition for prevention and treatment of prostate cancer

(B) composition for prevention and treatment of colon cancer

□) composition for prevention and treatment of lung cancer

(D) composition for prevention and treatment of breast cancer

(E) composition for prevention and treatment of ovary cancer

(F) composition for prevention and treatment of head-neck cancer

(G) composition for prevention and treatment of vulva cancer

(H) composition for prevention and treatment of bladder cancer

(I) composition for prevention and treatment of brain cancer

(J) composition for prevention and treatment of glioma

(K) composition for prevention and treatment of non-transmissible chronic diseases

(L) composition for prevention and treatment of viral diseases/AIDS

(M) composition for prevention and treatment of infectious diseases

(N) composition for prevention and treatment of autoimmune diseases

It is noted that claims 14-17 will be examined only as they are drawn to the elected invention.

4. Claims 1-3, 9 link inventions 19-36/(A)-(N). The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 1-3, 9. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP. 804.01.

Group 19. Claims 1-11, 14 drawn to a composition that potentiates immunogenicity comprising antigens wherein the incorporated ganglioside is GM1 or variant thereof, wherein the adjuvant is oily adjuvant, incomplete Freund□s Adjuvant, Montanide ISA51 classified in Class 530, subclass 350,

Class 536, subclass 23.1, Class 424, subclasses 1.11, 1.21. **Group 20.**

Claims 1-11, 14 drawn to a composition that potentiates immunogenicity comprising antigens wherein the incorporated ganglioside is GM1 or variant thereof, wherein the adjuvant is oily adjuvant, incomplete Freund□s Adjuvant, Montanide ISA51 classified in Class 530, subclass 350, Class 536, subclass 23.1, Class 424, subclasses 1.11, 1.21.

Group 21. Claims 1-11, 14 drawn to a composition that potentiates immunogenicity comprising antigens wherein the incorporated ganglioside is GM1 or variant thereof, wherein the adjuvant is oily adjuvant, incomplete Freund□s Adjuvant, Montanide ISA51 classified in Class 530, subclass 350, Class 536, subclass 23.1, Class 424, subclasses 1.11, 1.21.

Group 22. Claims 1-11, 14 drawn to a composition that potentiates immunogenicity comprising antigens wherein the incorporated ganglioside is GM3 or variant thereof, wherein the adjuvant is oily adjuvant, incomplete Freund□s Adjuvant, Montanide ISA51 classified in Class 530, subclass 350, Class 536, subclass 23.1, Class, 424, subclasses 1.11, 1.21.

Group 23. Claims 1-11, 14 drawn to a composition that potentiates immunogenicity comprising antigens wherein the incorporated ganglioside is GM3 or variant thereof, wherein the adjuvant is oily adjuvant, incomplete Freund□s Adjuvant, Montanide ISA51 classified in Class 530, subclass 350, Class 536, subclass 23.1, Class 424, subclasses 1.11, 1.21.

Group 24. Claims 1-11, 14 drawn to a composition that potentiates immunogenicity comprising antigens wherein the incorporated ganglioside is GM3 or variant thereof, wherein the adjuvant is oily adjuvant, incomplete

Freund□s Adjuvant, Montanide ISA51 classified in Class 530, subclass 350, Class 536, subclass 23.1, Class 424, subclasses 1.11, 1.21.

Group 25. Claims 1-9, 12-14 drawn to a composition that potentiates immunogenicity comprising antigens wherein the incorporated ganglioside is GM1 or variant thereof, wherein the adjuvant is polypeptide/cytosine/GMC classified in Class 530, subclass 350, Class 536, subclass 23.1, Class 424, subclasses 1.11, 1.21.

Group 26. Claims 1-9, 12-14 drawn to a composition that potentiates immunogenicity comprising antigens wherein the incorporated ganglioside is GM1 or variant thereof, wherein the adjuvant is polypeptide/cytosine/GMC classified in Class 530, subclass 350, Class 536, subclass 23.1, Class 424, subclasses 1.11, 1.21.

Group 27. Claims 1-9, 12-14 drawn to a composition that potentiates immunogenicity comprising antigens wherein the incorporated ganglioside is GM1 or variant thereof, wherein the adjuvant is polypeptide/cytosine/GMC classified in Class 530, subclass 350, Class 536, subclass 23.1, Class 424, subclasses 1.11, 1.21.

Group 28. Claims 1-9, 12-14 drawn to a composition that potentiates immunogenicity comprising antigens wherein the incorporated ganglioside is GM3 or variant thereof, wherein the adjuvant is polypeptide/cytosine/GMC classified in Class 530, subclass 350, Class 536, subclass 23.1, Class 424, subclasses 1.11, 1.21.

Group 29. Claims 1-9, 12-14 drawn to a composition that potentiates immunogenicity comprising antigens wherein the incorporated ganglioside is GM3 or variant thereof, wherein the adjuvant is

polypeptide/cytosine/GMC classified in Class 530, subclass 350, Class 536, subclass 23.1, Class 424, subclasses 1.11, 1.21.

Group 20. Claims 1-9, 12-14 drawn to a composition that potentiates immunogenicity comprising antigens wherein the incorporated ganglioside is GM3 or variant thereof, wherein the adjuvant is polypeptide/cytosine/GMC classified in Class 530, subclass 350, Class 536, subclass 23.1, Class 424, subclasses 1.11, 1.21.

Group 31. Claims 1-9, 12,14 drawn to a composition that potentiates immunogenicity antigens wherein the incorporated ganglioside is GM1 or variant thereof, wherein the adjuvant is polypeptide/chymosin classified in Class 530, subclass 350, Class 536, subclass 23.1, Class 424, subclasses 1.11, 1.21.

Group 32. Claims 1-9, 12,14 drawn to a composition that potentiates immunogenicity comprising antigens wherein the incorporated ganglioside is GM1 or variant thereof, wherein the adjuvant is polypeptide//chymosin classified in Class 530, subclass 350, Class 536, subclass 23.1, Class 424, subclasses 1.11, 1.21.

Group 33. Claims 1-9, 12,14 drawn to a composition that potentiates immunogenicity comprising antigens wherein the incorporated ganglioside is GM1 or variant thereof, wherein the adjuvant is polypeptide//chymosin classified in Class 530, subclass 350, Class 536, subclass 23.1, Class 424, subclasses 1.11, 1.21.

Group 34. Claims 1-9, 12,14 drawn to a composition that potentiates immunogenicity comprising antigens wherein the incorporated ganglioside is GM3 or variant thereof, wherein the adjuvant is polypeptide//chymosin

classified in Class 530, subclass 350, Class 536, subclass 23.1, Class 424, sublcasses 1.11, 1.21

Group 35. Claims 1-9, 12,14 drawn to a composition that potentiates immunogenicity comprising antigens wherein the incorporated ganglioside is GM3 or variant thereof, wherein the adjuvant is polypeptide//chymosin classified in Class 530, subclass 350, Class 536, subclass 23.1, Class 424, subclasses 1.11, 1.21.

Group 36. Claims 1-9, 12,14 drawn to a composition that potentiates immunogenicity comprising antigens wherein the incorporated ganglioside is GM3 or variant thereof, wherein the adjuvant is polypeptide//chymosin classified in Class 530, subclass 350, Class 536, subclass 23.1, Class 424, subclasses 1.11, 1.21.

For each of the inventions 19-36 above, restriction to one of the following is also required under 35 USC121. Therefore, election is required of one of inventions 19-36 **and** one of inventions (A)-(N).

(A) composition for prevention and treatment of prostate cancer

(B) composition for prevention and treatment of colon cancer

□) composition for prevention and treatment of lung cancer

(D) composition for prevention and treatment of breast cancer

(E) composition for prevention and treatment of ovary cancer

(F) composition for prevention and treatment of head-neck cancer

(G) composition for prevention and treatment of vulva cancer

(H) composition for prevention and treatment of bladder cancer

(I) composition for prevention and treatment of brain cancer

(J) composition for prevention and treatment of glioma

(K) composition for prevention and treatment of non-transmissible chronic diseases

(L) composition for prevention and treatment of viral diseases/AIDS

(M) composition for prevention and treatment of infectious diseases

(N) composition for prevention and treatment of autoimmune diseases

For each of the inventions 19-36 (A)-(N) above, restriction to one of the following is also required under 35 USC121. Therefore, election is required of one of inventions 19-36 **and** one of inventions (A)-(N) **and** one of inventions (I)-(xiv).

(I) antigen is nucleic acid

(ii) antigen is whole cell

(iii) antigen is whole cell lysate

(iv) antigen is polypeptide/nucleic acid

(v) antigen is polypeptide/nucleic acid/whole cell

(vi) antigen is polypeptide/nucleic acid/whole cell lysate

(vii) antigen is polypeptide/nucleic acid/whole cell/whole cell lysate

(viii) antigen is polypeptide/ whole cell

(ix) antigen is polypeptide/ whole cell lysate

(x) antigen is nucleic acid/ whole cell

(xi) antigen is nucleic acid/whole cell/whole cell lysate

(xii) antigen is nucleic acid/ whole cell lysate

(xiii) antigen is whole cell/whole cell lysate

(xiv) antigen is whole cell lysate/nucleic acid/whole cell

Group 37. Claim 15 drawn to a composition that potentiates immunogenicity comprising antigens for the treatment/prevention of viral diseases, classified in Class 530, subclass 350.

Group 38. Claim 15 drawn to a composition that potentiates immunogenicity comprising antigens for the treatment/prevention of bacterial diseases, classified in Class 530, subclass 350.

Group 39. Claim 16 drawn to a composition that potentiates immunogenicity comprising antigens for the treatment of AIDS, classified in Class 530, subclass 350.

Group 40. Claim 17 drawn to a composition that potentiates immunogenicity comprising antigens for the treatment of autoimmune diseases, classified in Class 530, subclass 350.

5. Claim 18, links inventions 41-51. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 18. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP 804.01.

Group 41. Claim 18 is drawn to a method for the prevention of prostate cancer comprising using a single composition of Groups 1-18(A-N)/19-36(A-N)(I)-(xiv), classified in Class 530, subclass 350, Class 536, subclass

23.1, Class 424, subclasses 1.11, 1.21. It is noted for Applicant□s information that this is not an election of species requirement, but rather an election of a Group for examination because each of the compositions of Groups 1-18(A-N)/19-36(A-N)(I)-(xiv) is a distinct invention for the reasons set forth below.

Group 42. Claim 18 is drawn to a method for the prevention of colon cancer comprising using a single composition of Groups 1-18(A-N)/19-36(A-N)(I)-(xiv), classified in Class 530, subclass 350, Class 536, subclass 23.1, Class 424, subclasses 1.11, 1.21. It is noted for Applicant□s information that this is not an election of species requirement, but rather an election of a Group for examination because each of the compositions of Groups 1-18(A-N)/19-36(A-N)(I)-(xiv) is a distinct invention for the reasons set forth below.

Group 43. Claim 18 is drawn to a method for the prevention of lung cancer comprising using a single composition of Groups 1-18(A-N)/19-36(A-N)(I)-(xiv), classified in Class 530, subclass 350, Class 536, subclass 23.1, Class 424, subclasses 1.11, 1.21. It is noted for Applicant□s information that this is not an election of species requirement, but rather an election of a Group for examination because each of the compositions of Groups 1-18(A-N)/19-36(A-N)(I)-(xiv) is a distinct invention for the reasons set forth below.

Group 44. Claim 18 is drawn to a method for the prevention of breast cancer comprising using a single composition of Groups 1-18(A-N)/19-36(A-N)(I)-(xiv), classified in Class 530, subclass 350, Class 536, subclass 23.1, Class 424, subclasses 1.11, 1.21. It is noted for Applicant□s

information that this is not an election of species requirement, but rather an election of a Group for examination because each of the compositions of Groups 1-18(A-N)/19-36(A-N)(I)-(xiv) is a distinct invention for the reasons set forth below.

Group 45. Claim 18 is drawn to a method for the prevention of ovary cancer comprising using a single composition of Groups 1-18(A-N)/19-36(A-N)(I)-(xiv), classified in Class 530, subclass 350, Class 536, subclass 23.1, Class 424, subclasses 1.11, 1.21. It is noted for Applicant□s information that this is not an election of species requirement, but rather an election of a Group for examination because each of the compositions of Groups 1-18(A-N)/19-36(A-N)(I)-(xiv) is a distinct invention for the reasons set forth below.

Group 46. Claim 18 is drawn to a method for the prevention of head-neck cancer comprising using a single composition of Groups 1-18(A-N)/19-36(A-N)(I)-(xiv), classified in Class 530, subclass 350, Class 536, subclass 23.1, Class 424, subclasses 1.11, 1.21. It is noted for Applicant□s information that this is not an election of species requirement, but rather an election of a Group for examination because each of the compositions of Groups 1-18(A-N)/19-36(A-N)(I)-(xiv) is a distinct invention for the reasons set forth below.

Group 47. Claim 18 is drawn to a method for the prevention of vulva cancer comprising using a single composition of Groups 1-18(A-N)/19-36(A-N)(I)-(xiv), classified in Class 530, subclass 350, Class 536, subclass 23.1, Class 424, subclasses 1.11, 1.21. It is noted for Applicant□s information that this is not an election of species requirement, but rather an

election of a Group for examination because each of the compositions of Groups 1-18(A-N)/19-36(A-N)(I)-(xiv) is a distinct invention for the reasons set forth below.

Group 48. Claim 18 is drawn to a method for the prevention of bladder cancer comprising using a single composition of Groups 1-18(A-N)/19-36(A-N)(I)-(xiv), classified in Class 530, subclass 350, Class 536, subclass 23.1, Class 424, subclasses 1.11, 1.21. It is noted for Applicant□s information that this is not an election of species requirement, but rather an election of a Group for examination because each of the compositions of Groups 1-18(A-N)/19-36(A-N)(I)-(xiv) is a distinct invention for the reasons set forth below.

Group 49. Claim 18 is drawn to a method for the prevention of brain cancer comprising using a single composition of Groups 1-18(A-N)/19-36(A-N)(I)-(xiv), classified in Class 530, subclass 350, Class 536, subclass 23.1, Class 424, subclasses 1.11, 1.21. . It is noted for Applicant□s information that this is not an election of species requirement, but rather an election of a Group for examination because each of the compositions of Groups 1-18(A-N)/19-36(A-N)(I)-(xiv) is a distinct invention for the reasons set forth below.

Group 50. Claim 18 is drawn to a method for the prevention of glioma cancer comprising using a single composition of Groups 1-18(A-N)/19-36(A-N)(I)-(xiv), classified in Class 530, subclass 350, Class 536, subclass 23.1, Class 424, subclasses 1.11, 1.21. It is noted for Applicant□s information that this is not an election of species requirement, but rather an election of a Group for examination because each of the compositions of

Groups 1-18(A-N)/19-36(A-N)(I)-(xiv) is a distinct invention for the reasons set forth below.

Group 51. Claim 18 is drawn to a method for the prevention of non-transmittable chronic diseases cancer comprising using a single composition of Groups 1-18(A-N)/19-36(A-N)(I)-(xiv), classified in Class 530, subclass 350, Class 536, subclass 23.1, Class 424, subclasses 1.11, 1.21. It is noted for Applicant□s information that this is not an election of species requirement, but rather an election of a Group for examination because each of the compositions of Groups 1-18(A-N)/19-36(A-N)(I)-(xiv) is a distinct invention for the reasons set forth below.

Group 52. Claim 19 is drawn to a method for the prevention of viral diseases comprising using a single composition of Groups 1-18(A-N)/19-36(A-N)(I)-(xiv), classified in Class 530, subclass 350, Class 536, subclass 23.1, Class 424, subclasses 1.11, 1.21. It is noted for Applicant□s information that this is not an election of species requirement, but rather an election of a Group for examination because each of the compositions of Groups 1-18(A-N)/19-36(A-N)(I)-(xiv) is a distinct invention for the reasons set forth below.

Group 53. Claim 19 is drawn to a method for the prevention of bacterial diseases comprising using a single composition of Groups 1-18(A-N)/19-36(A-N)(I)-(xiv), classified in Class 530, subclass 350, Class 536, subclass 23.1, Class 424, subclasses 1.11, 1.21. It is noted for Applicant□s information that this is not an election of species requirement, but rather an election of a Group for examination because each of the compositions of

Groups 1-18(A-N)/19-36(A-N)(I)-(xiv) is a distinct invention for the reasons set forth below.

Group 55. Claim 20 is drawn to a method for the prevention of auto-immune diseases comprising using a single composition of Groups 1-18(A-N)/19-36(A-N)(I)-(xiv), classified in Class 530, subclass 350, Class 536, subclass 23.1, Class 424, subclasses 1.11, 1.21. It is noted for Applicant□s information that this is not an election of species requirement, but rather an election of a Group for examination because each of the compositions of Groups 1-18(A-N)/19-36(A-N)(I)-(xiv) is a distinct invention for the reasons set forth below.

5. Claim 18, links inventions 41-51. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 18. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP. 804.01.

Group 41. Claim 18 is drawn to a method for the prevention of prostate cancer comprising using a single composition of Groups 1-18(A-N)/19-

36(A-N)(I)-(xiv), classified in Class 530, subclass 350, Class 536, subclass 23.1, Class 424, subclasses 1.11, 1.21. . It is noted for Applicant□s information that this is not an election of species requirement, but rather an election of a Group for examination because each of the compositions of Groups 1-18(A-N)/19-36(A-N)(I)-(xiv) is a distinct invention for the reasons set forth below.

Group 42. Claim 18 is drawn to a method for the prevention of colon cancer comprising using a single composition of Groups 1-18(A-N)/19-36(A-N)(I)-(xiv), classified in Class 530, subclass 350, Class 536, subclass 23.1, Class 424, subclasses 1.11, 1.21. It is noted for Applicant□s information that this is not an election of species requirement, but rather an election of a Group for examination because each of the compositions of Groups 1-18(A-N)/19-36(A-N)(I)-(xiv) is a distinct invention for the reasons set forth below.

Group 43. Claim 18 is drawn to a method for the prevention of lung cancer comprising using a single composition of Groups 1-18(A-N)/19-36(A-N)(I)-(xiv), classified in Class 530, subclass 350, Class 536, subclass 23.1, Class 424, subclasses 1.11, 1.21. It is noted for Applicant□s information that this is not an election of species requirement, but rather an election of a Group for examination because each of the compositions of Groups 1-18(A-N)/19-36(A-N)(I)-(xiv) is a distinct invention for the reasons set forth below.

Group 44. Claim 18 is drawn to a method for the prevention of breast cancer comprising using a single composition of Groups 1-18(A-N)/19-36(A-N)(I)-(xiv), classified in Class 530, subclass 350, Class 536, subclass

23.1, Class 424, subclasses 1.11, 1.21. It is noted for Applicant□s information that this is not an election of species requirement, but rather an election of a Group for examination because each of the compositions of Groups 1-18(A-N)/19-36(A-N)(I)-(xiv) is a distinct invention for the reasons set forth below.

Group 45. Claim 18 is drawn to a method for the prevention of ovary cancer comprising using a single composition of Groups 1-18(A-N)/19-36(A-N)(I)-(xiv), classified in Class 530, subclass 350, Class 536, subclass 23.1, Class 424, subclasses 1.11, 1.21. It is noted for Applicant□s information that this is not an election of species requirement, but rather an election of a Group for examination because each of the compositions of Groups 1-18(A-N)/19-36(A-N)(I)-(xiv) is a distinct invention for the reasons set forth below.

Group 46. Claim 18 is drawn to a method for the prevention of head-neck cancer comprising using a single composition of Groups 1-18(A-N)/19-36(A-N)(I)-(xiv), classified in Class 530, subclass 350, Class 536, subclass 23.1, Class 424, subclasses 1.11, 1.21. It is noted for Applicant□s information that this is not an election of species requirement, but rather an election of a Group for examination because each of the compositions of Groups 1-18(A-N)/19-36(A-N)(I)-(xiv) is a distinct invention for the reasons set forth below.

Group 47. Claim 18 is drawn to a method for the prevention of vulva cancer comprising using a single composition of Groups 1-18(A-N)/19-36(A-N)(I)-(xiv), classified in Class 530, subclass 350, Class 536, subclass 23.1, Class 424, subclasses 1.11, 1.21.It is noted for Applicant□s

information that this is not an election of species requirement, but rather an election of a Group for examination because each of the compositions of Groups 1-18(A-N)/19-36(A-N)(I)-(xiv) is a distinct invention for the reasons set forth below.

Group 48. Claim 18 is drawn to a method for the prevention of bladder cancer comprising using a single composition of Groups 1-18(A-N)/19-36(A-N)(I)-(xiv), classified in Class 530, subclass 350, Class 536, subclass 23.1, Class 424, subclasses 1.11, 1.21. It is noted for Applicant□s information that this is not an election of species requirement, but rather an election of a Group for examination because each of the compositions of Groups 1-18(A-N)/19-36(A-N)(I)-(xiv) is a distinct invention for the reasons set forth below.

Group 49. Claim 18 is drawn to a method for the prevention of brain cancer comprising using a single composition of Groups 1-18(A-N)/19-36(A-N)(I)-(xiv), classified in Class 530, subclass 350, Class 536, subclass 23.1, Class 424, subclasses 1.11, 1.21. It is noted for Applicant□s information that this is not an election of species requirement, but rather an election of a Group for examination because each of the compositions of Groups 1-18(A-N)/19-36(A-N)(I)-(xiv) is a distinct invention for the reasons set forth below.

Group 50. Claim 18 is drawn to a method for the prevention of glioma cancer comprising using a single composition of Groups 1-18(A-N)/19-36(A-N)(I)-(xiv), classified in Class 530, subclass 350, Class 536, subclass 23.1, Class 424, subclasses 1.11, 1.21. It is noted for Applicant□s information that this is not an election of species requirement, but rather an

election of a Group for examination because each of the compositions of Groups 1-18(A-N)/19-36(A-N)(I)-(xiv) is a distinct invention for the reasons set forth below.

Group 51. Claim 18 is drawn to a method for the prevention of non-transmittable chronic diseases cancer comprising using a single composition of Groups 1-18(A-N)/19-36(A-N)(I)-(xiv), classified in Class 530, subclass 350, Class 536, subclass 23.1, Class 424, subclasses 1.11, 1.21. It is noted for Applicant□s information that this is not an election of species requirement, but rather an election of a Group for examination because each of the compositions of Groups 1-18(A-N)/19-36(A-N)(I)-(xiv) is a distinct invention for the reasons set forth below.

Group 52. Claim 19 is drawn to a method for the prevention of viral diseases comprising using a single composition of Groups 1-18(A-N)/19-36(A-N)(I)-(xiv), classified in Class 530, subclass 350, Class 536, subclass 23.1, Class 424, subclasses 1.11, 1.21. It is noted for Applicant□s information that this is not an election of species requirement, but rather an election of a Group for examination because each of the compositions of Groups 1-18(A-N)/19-36(A-N)(I)-(xiv) is a distinct invention for the reasons set forth below.

Group 53. Claim 19 is drawn to a method for the prevention of bacterial diseases comprising using a single composition of Groups 1-18(A-N)/19-36(A-N)(I)-(xiv), classified in Class 530, subclass 350, Class 536, subclass 23.1, Class 424, subclasses 1.11, 1.21. It is noted for Applicant□s information that this is not an election of species requirement, but rather an election of a Group for examination because each of the compositions of

Groups 1-18(A-N)/19-36(A-N)(I)-(xiv) is a distinct invention for the reasons set forth below.

Group 54. Claim 20 is drawn to a method for the prevention of auto-immune diseases comprising using a single composition of Groups 1-18(A-N)/19-36(A-N)(I)-(xiv), classified in Class 530, subclass 350, Class 536, subclass 23.1, Class 424, subclasses 1.11, 1.21. It is noted for Applicant□s information that this is not an election of species requirement, but rather an election of a Group for examination because each of the compositions of Groups 1-18(A-N)/19-36(A-N)(I)-(xiv) is a distinct invention for the reasons set forth below.

6. Claims 18 and 21, links inventions 55-64. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 18 and 21. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP. 804.01.

Group 55. Claims 18 and 21-22 are drawn to a method for the treatment of prostate cancer comprising using a single composition of Groups 1-18(A-

N)/19-36(A-N)(I)-(xiv), classified in Class 530, subclass 350, Class 536, subclass 23.1, Class 424, subclasses 1.11, 1.21. It is noted for Applicant□s information that this is not an election of species requirement, but rather an election of a Group for examination because each of the compositions of Groups 1-18(A-N)/19-36(A-N)(I)-(xiv) is a distinct invention for the reasons set forth below.

Group 56. Claims 18 and 21-22 are drawn to a method for the treatment of colon cancer comprising using a single composition of Groups 1-18(A-N)/19-36(A-N)(I)-(xiv), classified in Class 530, subclass 350, Class 536, subclass 23.1, Class 424, subclasses 1.11, 1.21. It is noted for Applicant□s information that this is not an election of species requirement, but rather an election of a Group for examination because each of the compositions of Groups 1-18(A-N)/19-36(A-N)(I)-(xiv) is a distinct invention for the reasons set forth below.

Group 57. Claims 18 and 21-22 are drawn to a method for the treatment of lung cancer comprising using a single composition of Groups 1-18(A-N)/19-36(A-N)(I)-(xiv), classified in Class 530, subclass 350, Class 536, subclass 23.1, Class 424, subclasses 1.11, 1.21. It is noted for Applicant□s information that this is not an election of species requirement, but rather an election of a Group for examination because each of the compositions of Groups 1-18(A-N)/19-36(A-N)(I)-(xiv) is a distinct invention for the reasons set forth below.

Group 58. Claims 18 and 21-22 are drawn to a method for the treatment of breast cancer comprising using a single composition of Groups 1-18(A-N)/19-36(A-N)(I)-(xiv), classified in Class 530, subclass 350, Class 536,

subclass 23.1, Class 424, subclasses 1.11, 1.21. It is noted for Applicant□s information that this is not an election of species requirement, but rather an election of a Group for examination because each of the compositions of Groups 1-18(A-N)/19-36(A-N)(I)-(xiv) is a distinct invention for the reasons set forth below.

Group 59. Claims 18 and 21-22 are drawn to a method for the treatment of ovary cancer comprising using a single composition of Groups 1-18(A-N)/19-36(A-N)(I)-(xiv), classified in Class 530, subclass 350, Class 536, subclass 23.1, Class 424, subclasses 1.11, 1.21. It is noted for Applicant□s information that this is not an election of species requirement, but rather an election of a Group for examination because each of the compositions of Groups 1-18(A-N)/19-36(A-N)(I)-(xiv) is a distinct invention for the reasons set forth below.

Group 60. Claims 18 and 21-22 are drawn to a method for the treatment of head-neck cancer comprising using a single composition of Groups 1-18(A-N)/19-36(A-N)(I)-(xiv), classified in Class 530, subclass 350, Class 536, subclass 23.1, Class 424, subclasses 1.11, 1.21. It is noted for Applicant□s information that this is not an election of species requirement, but rather an election of a Group for examination because each of the compositions of Groups 1-18(A-N)/19-36(A-N)(I)-(xiv) is a distinct invention for the reasons set forth below.

Group 61. Claims 18 and 21-22 are drawn to a method for the treatment of vulva cancer comprising using a single composition of Groups 1-18(A-N)/19-36(A-N)(I)-(xiv), classified in Class 530, subclass 350, Class 536, subclass 23.1, Class 424, subclasses 1.11, 1.21.It is noted for Applicant□s

information that this is not an election of species requirement, but rather an election of a Group for examination because each of the compositions of Groups 1-18(A-N)/19-36(A-N)(I)-(xiv) is a distinct invention for the reasons set forth below.

Group 62. Claims 18 and 21-22 are drawn to a method for the treatment of bladder cancer comprising using a single composition of Groups 1-18(A-N)/19-36(A-N)(I)-(xiv), classified in Class 530, subclass 350, Class 536, subclass 23.1, Class 424, subclasses 1.11, 1.21. It is noted for Applicant□s information that this is not an election of species requirement, but rather an election of a Group for examination because each of the compositions of Groups 1-18(A-N)/19-36(A-N)(I)-(xiv) is a distinct invention for the reasons set forth below.

Group 63. Claims 18 and 21-22 are drawn to a method for the treatment of brain cancer comprising using a single composition of Groups 1-18(A-N)/19-36(A-N)(I)-(xiv), classified in Class 530, subclass 350, Class 536, subclass 23.1, Class 424, subclasses 1.11, 1.21. It is noted for Applicant□s information that this is not an election of species requirement, but rather an election of a Group for examination because each of the compositions of Groups 1-18(A-N)/19-36(A-N)(I)-(xiv) is a distinct invention for the reasons set forth below.

Group 64. Claims 18 and 21-22 are drawn to a method for the treatment of glioma cancer comprising using a single composition of Groups 1-18(A-N)/19-36(A-N)(I)-(xiv), classified in Class 530, subclass 350, Class 536, subclass 23.1, Class 424, subclasses 1.11, 1.21. It is noted for Applicant□s information that this is not an election of species requirement, but rather an

election of a Group for examination because each of the compositions of Groups 1-18(A-N)/19-36(A-N)(I)-(xiv) is a distinct invention for the reasons set forth below.

6. Claim 23, links inventions 65-66. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 23. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP. 804.01.

Group 65. Claim 23 is drawn to a method for the treatment of viral infection as disclosed in the specification, classified in Class 530, subclass 350, Class 536, subclass 23.1, Class 424, subclasses 1.11, 1.21.

Group 66. Claim 23 is drawn to a method for the treatment of bacterial infection as disclosed in the specification, classified in Class 530, subclass 350, Class 536, subclass 23.1, Class 424, subclasses 1.11, 1.21.

Group 67. Claim 24 is drawn to a method for the treatment of autoimmune disease, classified in Class 530, subclass 350, Class 536, subclass 23.1, Class 424, subclasses 1.11, 1.21.

8. The inventions are distinct, each from the other because of the following reasons:

Inventions 1-40 as disclosed are biologically and chemically distinct, unrelated in structure and function, made by and used in different methods and are therefore distinct inventions.

Inventions 41-67 are materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success.

The inventions of Groups 1-40 and 41-67 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (I) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP*. **806.05(h)**]. In the instant case the peptide/polypeptide/protein/nucleic acid/ whole cell/ whole cell lysate products can be used in a materially different process such as affinity chromatography.

Further, Inventions 1 through 40 are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the patentability of the combination does not rely necessarily and solely on the patentability of any one subcombination and (2) that the subcombination has utility by itself or in other combinations (MPEP. 806.05□)). In the instant case, the patentability of the combination does not rely necessarily and solely on the patentability of any one subcombination as clearly evidenced by the plural subcombinations claimed. Further, each of the subcombinations has utility by itself because each of the subcombinations are useful for preventing or treating a whole

laundry list of different diseases. Thus the claims are distinct as required by MPEP 806.05□).

9. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matter, restriction for examination purposes as indicated is proper.

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(h).

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

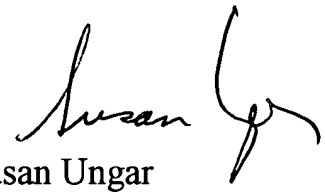
12. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is

(571) 272-0837. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at (571) 272-0787. The fax phone number for this Art Unit is (571) 273-8300

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Susan Ungar
Primary Patent Examiner
March 31, 2005